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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/560,407	11/08/2006	Stephan Nees	05157893	5484

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EXAMINER	
SAUCIER, SANDRA E	
ART UNIT	PAPER NUMBER
1651	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/560,407	NEES ET AL.	
	Examiner	Art Unit	
	Sandra Saucier	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-58* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-58* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 3.1 and 37 CFR 1.475.

In accordance with these rules, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1, 2, 20-22, drawn to a method for the endothelium preservation of hollow organs comprising contacting with a solution comprising (a) physiological electrolyte solution, at least 0.1% wt native albumin, nutrient substrate. Claim 2 appears to be improper since it replaces the native albumin with a serum, thus broadening the claim. However, for the sake of restriction and attempting to get the claims into rough form for examination, this group is considered to be directed towards a method using a composition comprising:
(a) a physiological electrolyte solution,
(b) at least 0.1% native albumin which can be substituted by autologous serum or homologous hemolysin-free serum,
(c) nutrient.

Group II, claims 1, 3-5, 11-13, 20-22, drawn to a method for the endothelium preservation of hollow organs comprising contacting with a solution comprising (a) physiological electrolyte solution, at least 0.1% wt native albumin, nutrient substrate. Claim 3 appears to be improper since it replaces the native albumin with a plasma preparation, thus broadening the claim. Also, claim 11 is so indefinite, it has been included. For the sake of restriction and attempting to get the claims into rough form for examination, this group is considered to be directed towards a method using a composition comprising:
(a) a physiological electrolyte solution,

(b) at least 0.1% native albumin which can be substituted by homologous anti-coagulatory-acting blood plasma preparation,
(c) nutrient.

Group III, claims 1, 6-8, 20-22, drawn to a method for the endothelium preservation of hollow organs comprising contacting with a solution comprising:
(a) physiological electrolyte solution,
(b) at least 0.1% wt native albumin,
(c) glutamine,
(d) glucose, and/or
(e) pyruvate.

Group IV, claims 1, 6, 7, 9, 20-22, drawn to drawn to a method for the endothelium preservation of hollow organs comprising contacting with a solution comprising:
(a) physiological electrolyte solution,
(b) at least 0.1% wt native albumin,
(c) glutamine,
(d) heparin or uric acid or ascorbate.

Group V, claims 1, 6, 7, 10, drawn to drawn to a method for the endothelium preservation of hollow organs comprising contacting with a solution comprising: (a) physiological electrolyte solution,
(b) at least 0.1% wt native albumin,
(c)glutamine,
(d) NaCl,
(e) KCl,
(f) MgSO4,
(g) KH2PO4,
(h) histidine-Cl,
(i) CaCl2.

Group VI, claims 1, 14, 15, 20-22, drawn to drawn to a method for the endothelium preservation of hollow organs comprising contacting with a solution comprising:
(a) physiological electrolyte solution,
(b) at least 0.1% wt native albumin,
(c) nutrient,
(d) endothelium promoting growth factor

Group VII, claims 1, 16, 17, 20-22, drawn to a method for the endothelium preservation of hollow organs comprising contacting with a solution comprising:
(a) physiological electrolyte solution,
(b) at least 0.1% wt native albumin,
(c) nutrient,
(d) flavonoid.

Group VIII, claims 1, 18, 20-22, drawn to a method for the endothelium preservation of hollow organs comprising contacting with a solution comprising:
(a) physiological electrolyte solution,
(b) at least 0.1% wt native albumin,
(c) nutrient,
(d) papaverin or adenosine.

Group IX, claims 1, 19-22, drawn to a method for the endothelium preservation of hollow organs comprising contacting with a solution comprising:
(a) physiological electrolyte solution,
(b) at least 0.1% wt native albumin,
(c) nutrient,
(d) potassium greater than 6mM.

Group X, claims 24, 25, 29-32, 35, drawn to a composition comprising:

(a) physiological electrolyte solution,
(b) at least about 0.1% wt native albumin, where the native albumin can be replaced with hemolysin-free serum or autologous serum, see notes under Group I above.
(c) about 0.5 to 10mM L-glutamine.

Group XI, claims 24, 26-32, 35, 38-40 drawn to a composition comprising:
(a) physiological electrolyte solution,
(b) at least about 0.1% wt native albumin, where the native albumin can be replaced with homologous anti-coagulatory blood plasma preparation, see notes under Group II above.
(c) about 0.5 to 10mM L-glutamine. It is note that claim 39 recites "a method", but this interpreted to be an error and the claim is intended to be a composition claim.

Group XII, claims 24, 29-33, 35, drawn to a composition comprising:
(a) physiological electrolyte solution,
(b) at least about 0.1% wt native albumin,
(c) about 0.5 to 10mM L-glutamine
(d) glucose or pyruvate.

Group XIII, claims 24, 29-32, 34, 35, drawn to a composition comprising:
(a) physiological electrolyte solution,
(b) at least about 0.1% wt native albumin,
(c) about 0.5 to 10mM L-glutamine
(d) heparin or uric acid or ascorbate.

Group XIV, claims 24, 29-32, 35, 36, 37, drawn to a composition comprising:
(a) physiological electrolyte solution,
(b) at least about 0.1% wt native albumin,
(c) about 0.5 to 10mM L-glutamine

(d) antibiotics

Group XV, claims 24, 29-32, 35, 41, 42, drawn to a composition comprising:
(a) physiological electrolyte solution,
(b) at least about 0.1% wt native albumin,
(c) about 0.5 to 10mM L-glutamine,
(d) endothelium-promoting growth factors.

Group XVI, claims 24, 29-32, 35, 43, 44, drawn to a composition comprising:
(a) physiological electrolyte solution,
(b) at least about 0.1% wt native albumin,
(c) about 0.5 to 10mM L-glutamine
(d) flavonoid.

Group XVII, claims 24, 29-32, 35, 45, drawn to a composition comprising:
(a) physiological electrolyte solution,
(b) at least about 0.1% wt native albumin,
(c) about 0.5 to 10mM L-glutamine
(d) papaverin or adenosine.

Group XVIII, claims 24, 29-32, 35, 46, drawn to a composition comprising:
(a) physiological electrolyte solution,
(b) at least about 0.1% wt native albumin,
(c) about 0.5 to 10mM L-glutamine
(d) potassium more than about 6mM.

Group XIX, claims 47-51, 55, drawn to an apparatus for treatment of isolated biological vessels.

Group XX, claims 52, 56, drawn to use claims for the preservation of endothelium in hollow organs or biological vessels.

Group XXI, claims 53, 57, drawn to use claims for maintenance or repair of endothelial tissue in hollow organs or biological vessels.

Group XXII, claims 54, 58, drawn to use claims for therapy or prevention of vascular occlusions in isolated hollow organs of biological vessels.

ELECTION OF SPECIES

In addition if Groups I-IX are elected, an election of species is also required. This application contains claims directed to the following patentably distinct species, heart, intestine, uterus, kidney, bladder, lung, liver, spleen, blood vessels, lymphatic vessels. The species are independent or distinct because claims to the different species recite the mutually exclusive characteristics of such species. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 1 is generic.

There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the**

claims encompassing the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

Applicants have formed a complex tree of multiple diverting points in both the method and composition claims. This has necessitated a number of groups in the restriction requirement. For example, a composition A may not be restricted from compositions A+B, or from A+B+C, or from A+B+C+D as these form a tree of further limitations. However, compositions A+B and A+C and A+D, etc. are distinct compositions and may be properly restricted.

(a) An international or national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept. Where a group of inventions is claimed in an application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those invention involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

(b) An international or a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories:

(1) a product and a process specially adapted for the manufacture of said product; or

(2) a product and a process of use of said product; or

(3) a product, a process specially adapted for the manufacture of the said product, and a use of the said product; or

(4) a process and an apparatus or means specifically designed for carrying out said process; or

(5) a product, a process specially adapted for the manufacture of the said product and an apparatus or means specifically designed for carrying out said process.

(c) If an application contains claims to more or less than one of the combinations of categories of invention set forth in paragraph (b) of this section, unity of invention might not be present.

PCT Rule 13.2 does not provide for multiple compositions or multiple methods of use within a single application. Thus, the first appearing composition is combined with a corresponding first method of use and the additional composition and method claims each constitute a separate group.

In addition to the requirement that a group of inventions must belong to one of the specific categories provided by PCT Rule 13.2, the inventions in the category, such as a composition and a method of use of the composition, must have a special technical feature that unites them. See Patent Rules 1.475, where a special technical feature is a contribution OVER THE PRIOR ART.

Thus, the inventions listed as Groups I-XXII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features as demonstrated above. Since the composition AS CLAIMED, physiological electrolyte solution, at least 0.1% native albumin, nutrient substrate is known in the art, see WO 02/35929, abstract, no special technical feature unites these inventions in a category.

The expression "special technical feature" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art (PCT Rule 13.2). Thus, a feature found in the prior art cannot be considered to be a special technical feature.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit

1651. The supervisor for 1651 is M. Wityshyn, (571) 272-0926. The normal work schedule for Examiner Saucier is 8:30 AM to 6:00 PM Monday and Tuesday and 8:30 AM-12:30 PM on Wednesday.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Saucier whose telephone number is (571) 272-0922. The number of the Fax Center for the faxing of official papers is (571) 272-8300.

/Sandra Saucier/
Primary Examiner
Art Unit 1651